

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Michael Harris } } Art Unit: 3771  
Serial No. 10/660,429 } } Examiner: Kristen Clarette Matter  
Filing Date: September 12, 2003 } }  
Title: Methods for the treatment of HIV and other viruses

Certificate of Mailing Under 37 CFR §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service using First Class Service under 37 C.F.R. § 1.8 on the date indicated below and is addressed to MailStop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

Date: October 21, 2008

United States Postal Service using First Class  
addressed to Mail Stop Amendment, Commissioner

**AMENDMENT UNDER 37 CFR § 1.111**

Mail Stop Amendment  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated August 4, 2008, having a three (3) month shortened statutory period set to expire November 4, 2008, this Response is being timely filed. No fees are believed due at this time. By way of this paper, Applicant's representative would also like to request an in-person interview with the Examiner to discuss the present amendment. **Amendments to the Claims** begin on page 2 of this paper. **Remarks/Arguments** begin on page 6 of this paper.

**IN THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A method for increasing a ratio of CD4/CD8 lymphocytes, reducing a viral load and restoring an immune system, including lymph node architecture, of a person infected with at least one virus, ~~such as HIV, including HIV~~, wherein the person is placed in a hyperbaric chamber and exposed to one or more gases at one or more atmospheric pressures for one or more time-periods, wherein the one or more gases is nitrogen, surface air, an inert gas, nitrous oxide or another anesthetic, ~~and wherein the one or more gases, except for air, make up 5% or more of gases in the chamber, further wherein at least one of the one or more gases is nitrogen or nitrous oxide~~, the method comprising the steps of:

selecting the one or more gases to be used in the hyperbaric chamber;

selecting the one or more pressures to be used in the hyperbaric chamber;

selecting the one or more time-periods that the patient is exposed to the selected gas(es) and pressure(s) while in the hyperbaric chamber;

placing the patient in, or having the patient enter, the hyperbaric chamber wherein monitoring of the patient's vital signs may optionally be provided; and,

exposing the patient to the selected one or more gases, at the selected one or more pressures for the selected one or more time-periods.

2. (Canceled)

3. (Currently Amended) The method of claim 1, wherein the one or more pressures selected ~~is greater than are at least~~ one atmosphere.

4. (Original) The method of claim 1, wherein the step of exposing the patient is repeated two or more times.

5. (Original) The method of claim 1, wherein the one or more pressures selected are equal to an underwater pressure of between 70 and 165 feet.

6. (Original) The method of claim 1, wherein the duration of exposure is repeated daily for 3 to 21 days.
7. (Original) The method of claim 1, further comprising the step of:  
creating an exposure chart for the person wherein the chart lists the time-periods the person is to be exposed to the selected one or more pressures and selected one or more gases, and wherein the exposure chart is at least partly based on a condition of the person.
8. (Original) The method of claim 1, wherein the step of placing the patient in the chamber further comprises:  
placing more than one person in the chamber.
9. (Currently Amended) A method for preventing reproduction of a virus wherein a pressurized chamber is used to cause an atom, molecule or compound from gases that fills the chamber, or from within a patient's body, into an attachment site on a cell wall of a living cell or into a receptor unit on the virus, whereby the atom, molecule or compound prevents the virus from replicating by preventing the virus from attaching to the attachment site of the living cell, the method comprising the steps of:  
selecting one or more gases to be used inside the chamber, wherein the one or more gases ~~is are~~ nitrogen, surface air, an inert gas, nitrous oxide or another anesthetic, ~~and wherein the one or more gases, except for air, make up 5% or more of gases in the chamber, further wherein at least one of the one or more gases is nitrogen or nitrous oxide;~~  
selecting one or more pressures to expose the patient to while inside the chamber;  
selecting one or more time-periods, wherein each time-period is associated with a selected pressure; and,  
exposing the patient to the one or more selected gases in the chamber at a selected pressure for the associated time-period.
10. (Canceled)

11. (Original) The method of claim 9, wherein the step of exposing the patient is repeated two or more times.

12. (Currently Amended) The method of claim 9, wherein the one or more selected pressures are ~~greater than~~ at least one atmosphere.

13. (Original) The method of claim 9, wherein more than one patient is placed in the chamber and the more than one patients are simultaneously exposed to the gases and pressures inside the chamber.

14. (Original) The method of claim 9, wherein the patient remains at the selected pressure for the selected time-period and the patient is subsequently returned to normal atmospheric pressure (1 ata) during a decompression time and wherein the decompression time is at least partly based on a standard decompression table.

15. (Original) A method for the treatment of patients infected with a virus, including HIV, involving the inhalation of nitrous oxide at normal atmospheric pressure wherein inhaled nitrogen blocks virus-host attachment sites and prevents the virus from replicating thereby reducing viral load and restoring a patient's immune system, the method comprising the steps of:

selecting an inhalation period, wherein the patient inhales gases comprising nitrous oxide during the inhalation period;

selecting a number of times to repeat the inhalation period;

having the patient inhale the gases comprising nitrous oxide for the selected inhalation period and, repeating the step of having the patient inhale the gases for the selected number of times.

16. (Original) The method of claim 15, wherein a subsequent inhalation period is a different length of time than a previous inhalation period.

17. (Original) The method of claim 15, wherein different percentages of nitrous oxide are

used during different inhalation periods.

18. (Original) The method of claim 15, wherein the inhaled nitrous oxide is provided in a concentration of 5% or more.

19. (Canceled)

20. (Canceled)

21. (Newly Added) The method of claim 1, further wherein when the one or more gases are nitrogen, an inert gas, nitrous oxide or another anesthetic gas, the one or more gases make up 5% or more of the gases in the chamber.

22. (Newly Added) The method of claim 9, further wherein when the one or more gases are nitrogen, an inert gas, nitrous oxide or another anesthetic gas, the one or more gases make up 5% or more of the gases in the chamber.

## **Remarks**

Applicant notes that this paper is in response to a third non-final Office Action and that the previous arguments in response to the second non-final Office Action were stated by the Examiner in the present Office Action to be moot because of new grounds of rejection.

Claims 1-20 were pending and are under examination. Claims 2 and 10 were previously canceled. Claims 19 and 20 are canceled herein and their subject matter incorporated into claims 3 and 12 respectively. New claims 21 and 22 have been added.

Claims 1 and 9, and their dependent claims, 3 and 12, respectively, are currently amended to more clearly point out the subject matter being claimed. Support can be found in the claims as originally filed and in the specification. No new subject matter has been introduced by way of these amendments, which are fully supported by the specification and claims as filed.

New dependent claims 21 and 22 have been added. They incorporate similar elements deleted from claims 1 and 9, from which they depend, respectively. No new subject matter has been introduced by way of these amendment, which are fully supported by the specification and claims as filed.

On page 11, the Examiner states that Applicant's arguments with respect to claims 1, 3-9 and 11-20 have been considered but are moot in view of the new ground(s) of rejection.

Applicant points out that there is an Interview Summary (described below) and in that Summary the arguments did overcome the art and rejections. The Summary is described below.

### **Response to Interview Summary**

Applicant thanks the Examiner and her supervisor for conducting the personal interview with Applicant and Applicant's representative on July 2, 2008. Applicant notes that an Interview Summary was issued by Examiner Matter on July 7, 2008. Examiner agreed that Risley et al. (U.S. Pat. No. 7,198,045) was an improper reference and not available as prior art as was argued by Applicant. Examiner understood that the claims as amended did not include the use of 100% oxygen and stated that this amendment would also overcome the rejection as to Reillo.

Applicant respectfully points out that no claims were rejected solely as to Reillo. Claims were only rejected based on the combination of Reillo and Risley. Because Risley was an improper prior art reference, as admitted by the Examiner, the combination failed and thus the rejection failed. Although Applicant also agrees that no claims are rendered obvious as to Reillo, Applicant respectfully requests that Examiner reiterate that there was no rejection as to Reillo,

even though the Examiner states in the current Office Action that the arguments provided in the Response to the last Office Action are moot because there are new grounds of rejection.

### **Response to Claim Objection**

Examiner alleges that there is a typographical error in claim 14, line 3 where the abbreviation/acronym “ata” is used and asserts that it should be changed to “atm”. Applicant points out that either can be used and specifically points to page 18, lines 1-3 of the specification which states “Pressure inside chamber 200 can be measured in atmospheres (**atm or ata**) or by the equivalent water pressure at a specified depth in feet (ft).” (emphasis added). For these reasons Applicant asserts that the use of “ata” is correct and requests withdrawal of the objection as to claim 14.

### **Response to Rejection of Claims 1, 3-9, 11-14, 19 and 20 under 35 U.S.C. § 112, second paragraph, indefiniteness**

Examiner asserts that the phrase “such as” in claim 1, line 3 renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention, citing MPEP § 2173.05.

Although not necessarily agreeing with the reasoning of the Examiner as to the use the phrase “such as HIV”, in order to expedite the prosecution of the application Applicant has deleted the phrase from claim 1 and has replaced it with the phrase “including HIV”. This is the same phrase used in claim 15 and Applicant requests that the rejection as to use of the phrase “such as HIV” is now moot and requests that the rejection be withdrawn.

Examiner further asserts that regarding claims 1 and 9, lines 6 and 9, respectively, the limitation “wherein the one or more gases, except for air, make up 5% or more of the gases” is somewhat unclear because the examiner is unsure whether the air is referring back to the surface air that was previously claimed. Additionally, Examiner states that if the surface air is being referred back to how could it not make up 5% or more of the gases because it appears that when surfaces is being used in hyperbaric chambers that it makes up 100% of the gases.

The use of the phrase “wherein the one or more gases, except for air, make up 5% or more of the gases” and the context in which it is used, specifically as it relates to air, is found throughout specification as filed, but particularly at page 12, lines 15-20, page 26, lines 7-9 and

the claims as filed. The context relates to a subset of parameters where in one aspect when nitrogen, an inert gas, nitrous oxide or another anesthetic were used, they comprised 5% or more of the gas in the chamber. For example, Figure 3 describes nitrous oxide at 10%, and the group “Nitrogen” used in Figure 6 used 93.5% nitrogen gas (see page 20, lines 22-24). However, surface air can be varied in concentration because when more than one gas is used, and that includes surface air, it precludes any gas from being 100%. For example, in Figs. 3 and 4 the nitrogen (nitrous oxide) concentrations are exemplified at 10% and 20%, respectively, meaning that the remaining gases comprise at total of 90 or 80%, respectively. This demonstrates that in one embodiment when gases other than air are used they can make up 5% or more of the gas in the chamber. In fact, the claims encompassing this element were originally dependent claims. To that end, to clarify the claims Applicant has deleted the phrase from independent claims 1 and 9, and has added the phrase to new dependent claims 21 and 22, depending from claims 1 and 9, respectively, and has revised the phrase so that it is more clear and does not have the reference to air. This amendment is supported by the specification and to the claims as filed. Applicant submits that these amendments make the rejection moot and requests that it be withdrawn.

Examiner then asserts that the dependent claims of claim 1 (e.g., 3-8 and 19) are rejected for the reason claim 1 is rejected and that the dependent claims of claim 9 (e.g., 11-14 and 20) are rejected for the reason claim 9 is rejected.

Applicant submits that the amendments as to independent claims 1 and 9 overcome the 112 rejections, which in turn render the rejections as to their dependent claims moot, including newly added claims 21 and 22, and Applicant requests that the indefiniteness rejections be withdrawn. Claims 19 and 20 have been canceled herein, therefore the rejection as to these claims is now moot and Applicant requests that the rejection as to claims 19 and 20 be withdrawn.

#### **Response to Rejection of Claims 15-18 under 35 U.S.C. § 103(a), obviousness**

Examiner has rejected claims 15-18 as allegedly obvious over Watt (US Pat. No. 4,554,916). The Examiner asserts that as to claims 15 and 16, Watt discloses a therapeutic inhaler for the delivery of nitrous oxide at atmospheric pressure (citing the abstract). Examiner admits that Watt does not disclose that the device is used for treating virus or HIV, but asserts that the method steps would have directly resulted from use of the device (i.e., upon inhalation of

th nitrous oxide, viruses, within the patient's body would be treated). The examiner then asserts that the mechanisms of treatment of virus (i.e., inhaled nitrogen blocking virus-host attachment sites to prevent replication) in the present claims would be inherently carried out by the patient inhaling the nitrous oxide. The Examiner then states that to the extent, if any, that Watt is silent as to selecting an inhalation period and repeating the inhalation step, it would have been obvious to one of ordinary skill in the art at the time of the invention to have had a patient breath the nitrous oxide for repeated periods of time.

Applicant traverses the rejection for reasons described below and asserts that based upon the claim amendments and the arguments provided herein, the claims as amended, as well as the newly added claims, are in condition for allowance.

First, Applicants point out that the “teaching, suggesting, and motivation” test was not overruled by the Supreme Court in the KSR case (*KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007)), as described below, and that these factors are still useful in an obviousness analysis. Additionally, as stated in MPEP 2143 regarding the burden of the Examiner “The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” Applicants submit that this burden has not been met.

In *KSR*, the US Supreme Court restated the requirements for a finding of obviousness. Encouraging the application of common knowledge and common sense, the Court took care to guard against hindsight bias and *ex post* reasoning and to distinguish the predictable from the unpredictable arts ("If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability." [Emphasis added]). The field of pharmaceuticals can only be viewed as a highly unpredictable art (in contrast to the throttle pedals of KSR). Because the skilled person in this art understands the significant unpredictability associated with pharmaceuticals and their methods of use, the rejection of the claims under §103 could only have been made with hindsight bias and *ex post* reasoning in the face of the Applicant's success.

When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision

afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined (MPEP § 2141 II).

Second, Applicant points out that the Examiner is applying inherency statements in an obviousness rejection and respectfully submits that such statements should be restricted to anticipation rejections.

Preliminarily, the three-prong test which must be met for a reference or a combination of references to establish a *prima facie* case of obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142.

Additionally, MPEP § 2143.01 provides: “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).” However, the “teaching, suggestion, motivation” test (“TSM”) must not be rigidly applied (*KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007)), but to determine **whether there is an apparent reason to combine the known elements in the fashion as claimed, the analysis should be made explicit by the Examiner** (*Id.*) (emphasis added)

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested, by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) ; MPEP § 2143.03. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ; MPEP § 2143.03. As part of establishing a *prima facie* case of obviousness, the Examiner’s analysis must show that some objective teaching in the prior art or some knowledge generally

available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.* The court in *Fine* stated that:

Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id.* (emphasis in original).

The test for obviousness under §103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir.1985). The Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103, recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990). The fact that a reference teaches away from a claimed invention is highly probative that the reference would not have rendered the claimed invention obvious to one of ordinary skill in the art. *Stranco Inc. v. Atlantes Chemical Systems, Inc.*, 15 USPQ2d 1704, 1713 (Tex. 1990). When the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *KSR Int'l Co.*, 550 U.S. \_\_\_\_ (2007)(slip opinion at 12)(citing *United States v. Adams*, 383 U.S. 39, 51-51 (1966)).

Further, the Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. See *KSR Int'l Co.*, 550 U.S. \_\_\_\_ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)); *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002), and more recently in *Ex parte Wada and Murphy* (BPAI Appeal No. 2007-3733, 1/14/08). Conclusions of obviousness must be based on facts, not generality. *In re Warner*, 379 F.2d 1011, 1017 (C.C.P.A. 1967); *In re Freed*, 425 F.2d 785, 787 (C.C.P.A. 1970). Additionally, an Examiner must specifically articulate a

sufficient reason why one skilled in the art would have modified the art and arrived at the presently claimed subject matter. *Ex parte Penhasi*, BPAI Appeal No. 2007-2534 (12/13/07).

The requirement of objective evidence in an obviousness rejection has been further supported by recent decisions of the Board of Patent Appeals and Interferences. For example, in *Ex parte Rathman*, BPAI Appeal No. 2007-4156, 12/11/07, the Board stated that the mere recognition that “[t]he genetic modification of cells has been routine in the art for some 20+ years. . . does not mean that a person of ordinary skill in the art would willy-nilly modify any cell with any gene to treat a disease”. The Board in *Ex parte Rathman* also noted that “the inferences and creative steps derived from the prior art on this record fail to lead a person of ordinary skill in the art to Appellants’ claimed invention”. The Board then asserted that the **Examiner must identify a viable reason** why a person of ordinary skill would have been led to combine the teachings of the cited art in the manner set forth by the Appellants’ claimed invention. Finally, the Examiner must avoid hindsight. *In re Bond* at 834. (emphasis added)

Additionally, MPEP 2143.02 requires that there be **at least some degree of predictability for there to be a reasonable expectation of success** (*In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (emphasis added). More recently, the Board held that optimization of a known result-effective variable in a given range is **obvious “only” when it is reasonably expected that an improvement will arise in that range** (*Ex Parte Atkinson and Benedict*, BPAI Appeal No. 2007-3900, 12/18/07, citing *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) and *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)) (emphasis added). That predictability must be determined at the time the invention was made (*Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986).

None of these criteria have been met here. Of course these are guiding principles for analyzing obviousness, but Applicant submits that under any analysis, the cited reference does not render the claims obvious for the following reasons.

Regarding the rejection of “independent” claim 15, Applicant points out that each and every element of claim must be taught or suggested by the prior art, and Applicant asserts that this reference does not. Applicant respectfully submits that the Examiner has not met the requirements of *KSR*, *Ex Parte Rathman*, and *Ex Parte Penhasi* as to providing sufficient and explicit reasonings and explanations as to why one skilled in the art would be motivated to modify Watt or that there would be a reasonable expectation of success, because Watt clearly

does not teach each and every element of the invention as claimed. Furthermore, the present application discloses the unexpected discovery that nitrous oxide effects the ability of viruses to attach to viral receptor sites, which in turn effects viral replication, which is not taught or suggested by Watt.

The Examiner has made no specific correlation, and cannot, between the device of Watt and the method which is claimed in the present application. As described above, the Examiner asserts that, as to claims 15 and 16, Watt discloses a therapeutic inhaler for the delivery of nitrous oxide at atmospheric pressure (citing the abstract). However, the Examiner then admits that Watt does not disclose that the device is used for treating virus or HIV, but asserts that the method steps would have directly resulted from use of the device (i.e., upon inhalation of nitrous oxide, viruses, within the patient's body would be treated). The examiner then asserts that the mechanisms of treatment of virus (i.e., inhaled nitrogen blocking virus-host attachment sites to prevent replication) in the present claims would be inherently carried out by the patient inhaling the nitrous oxide. Applicant submits that the analysis does not rise to the level required because there is no specific objective evidence record provided regarding direct results or inherency as applicable to treating patients infected with a virus, or the other elements claimed. For example, nowhere in Watt was there a discussion or implication of treating a patient infected with a virus. Even if a subset of Watt's intended targets had a virus, there was no suggestion of such and the populations would not be the same based on the types of treatment discussed in Watt's background. Watt's only reference to patient treatment was in the background and it referred to what others had done. As described above, the Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to modify or combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. See *KSR Int'l Co.*, 550 U.S. \_\_\_\_ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)); *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). Conclusions of obviousness must be based on facts, not generality. *In re Warner*, 379 F.2d 1011, 1017 (C.C.P.A. 1967); *In re Freed*, 425 F.2d 785, 787 (C.C.P.A. 1970). These rejections provide no objective evidence record and it does not provide reasoning, based on evidence, to support a finding of obviousness. There is no implied or explicit motivation for modifying Watt to arrive at the present invention, and there would be absolutely no reasonable expectation of success based on what is taught by Watt.

Contrary to the assertion of the Examiner, Applicant submits that Watt's only suggestion for use is directed to treating patients suffering from psychoneurosis, etc. with **combinations of carbon dioxide, oxygen**, and nitrous oxide using a complicated rotary gas proportioning inhalator (see abstract, column 1, lines 10-13, lines 58-60, column 2, lines 63-65) which is used to mix "at least three gases" (see claim 1, line 2 of Watt). The present claims do not recite carbon dioxide or oxygen as taught by Watt. The use is only described in the Background of the Watt. The only Watt reference to a beneficial use of the device in the Summary, Detailed Description, or in the Claims is to a "life sustaining" or "life supporting" level of oxygen. The Watt claims are all device claims and do not recite a type of disease or disorder to be treated. Again, what is disclosed in Watt would provide no motivation to treat patients infected with a virus as claimed, an no predictability.

Claim 1 of Watt specifically recites a combination of at least three gases and the disclosure teaches carbon dioxide and oxygen as two of the three gases. Applicant suggests that the required use of at least three gases, specifically when one of them is carbon dioxide, teaches away from the present invention. Even assuming arguendo that it does not, there would be no reasonable expectation of success. Additionally, the gist of the Watt patent is directed to the device itself and all the claims are for the device which is a proportional rotary mixing device which can mix six gases at a time, and in fact claims that at least three gases must be mixed. Furthermore, the only reference to a use is some Background information. Moreover, the patent contains no data indicating that the device works, much less that it will work for a purpose, and a purpose is only speculated in the patent.

The present application is the first to disclose that the use of an inhaled nitrogen or other nitrogen containing gas, such as nitrous oxide, is effective in treating viral infection, and is in fact unexpectedly much more effective than the use of hyperbaric oxygenation alone. The present invention, as recited in claim 15, is directed to a method for treating patients infected with a virus, including HIV, involving the inhalation of nitrous oxide at normal atmospheric pressure wherein inhaled nitrogen blocks virus-host attachment sites and prevents the virus from replicating, reducing viral load and restoring a patient's immune system, and comprises the steps of selecting an inhalation period, wherein the patient inhales gases comprising nitrous oxide during the inhalation period; selecting a number of times to repeat the inhalation period; having the patient inhale the gases comprising nitrous oxide for the selected inhalation period and,

repeating the step of having the patient inhale the gases for the selected number of times. In order for Watt to render this claim obvious, it must teach or suggest each and every element of the claims, and it does not because it makes no reference to treating patients infected with a virus, nor does it teach the use of nitrous oxide to treat a viral infection, nor does it teach or suggest the use of nitrous oxide to block virus-host attachment sites, nor does it teach or suggest reducing a viral load, nor does it teach or suggest restoring a patient's immune system.

Furthermore, not only does it not teach or suggest any of these elements, it does not teach or suggest any of the steps for such treatment as they specifically relate to the treatment recited in independent claim 15 and in its dependent claims 16-18. According to MPEP §2143.03, all claim limitations must be considered when an obviousness rejection is being contemplated. Applicant submits that not all claim limitations were considered in the context of the claim.

As discussed in *KSR*, treatments such as these in the pharmaceutical and biological arts are highly unpredictable and hindsight bias and *ex post* reasoning in the face of Applicant's success is not allowed. Applicant submits that based on what was known at the time of this invention, it is not possible for Watt to render claims 15-18 obvious. There was no motivation to modify Watt, there was no reasonable expectation of success or predictability, it did not teach anything closely related to what is presently claimed, and a hindsight analysis cannot lead to the use of Watt.

MPEP §2143.01, III, again referring to *KSR*, states that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless >the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_, \_\_, 82 USPQ2d 1385, 1396 (2007)". Applicant submits that even if there were a motivation to modify Watt or there were teachings or suggestions to do so, it would have been unpredictable to do so because there was no evidence that the device or an intended use was even related to treating a patient with a virus, and even if it were suggested there would have been no way of predicting success.

Therefore, even under *KSR* standards the Watt reference does not render the claims obvious.

### Inherency

Additionally, Applicant submits that the Examiner has improperly applied an inherency rejection. Applicant respectfully submits that the Examiner's application of the inherency standard is incorrect, and that the claimed methods are not inherent based on the disclosure of Watt or any other of the cited references for the other rejections described below. Furthermore, the inherency standard, when used, is proper for an anticipation rejection, not an obviousness rejection. Assuming arguendo that an inherency rejection were proper here, Applicants submit that there is no basis for such a rejection here and address it from several perspectives below.

Applicant asserts that the statements by the Examiner appear to be those where the Examiner is suggesting either that she is relying on common knowledge or is taking Official Notice and Applicant submits that this has not been properly done. When such occurs in an obviousness rejection, certain requirements must be met by the Examiner. The Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *See KSR Int'l Co.*, 550 U.S. \_\_\_\_ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)); *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). Conclusions of obviousness must be based on facts, not generality. *In re Warner*, 379 F.2d 1011, 1017 (C.C.P.A. 1967); *In re Freed*, 425 F.2d 785, 787 (C.C.P.A. 1970). More recently, the Federal Circuit has further explained the reasons that inherent and obviousness are separate and require different rejections (*Cohesive Technologies, Inc. v. Waters Corp.*, (Fed. Cir. 2008)).

According to MPEP §, 2144.03, the standard of review applied to findings of fact is the "substantial evidence" standard under the Administrative Procedure Act (APA). See *In re Gartside*, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). See also MPEP § 1216.01. The assertions of the Examiner as to inherency of predictable treatments of viruses using nitrogen containing gases as claimed (nitrous oxide in claim 15) are not common knowledge and Applicant requests that Examiner provide the Official Notice and explicit reasoning and evidence required when such an assertion is made by an Examiner. MPEP §, 2144.03(C)

Regarding an inherent feature or characteristic, MPEP § 2112 explains that the "express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102," but MPEP § 2112(IV-V) requires that the Examiner must provide a

rationale for rejection based on an “inherent property.” Applicants respectfully submit that in the present Office Action, the Examiner has not met this burden. This is because the Examiner has not provided evidence or reasoning tending to show that the missing claimed method of use is necessarily present in the disclosure of the cited reference, either alone or in combination. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The *Robertson* court also stated that “[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Id.* (emphasis added). The present claims claim a method of treating a patient infected with a virus involving the inhalation of nitrous oxide at normal atmospheric pressure to block virus-host attachment site, to prevent the virus from replication, to reduce viral load and to restore the patient’s system. These methods are not inherent in the method disclosed by the cited reference. The Examiner has not provided evidence that one of ordinary skill in the art would have recognized that the disclosure of Watt teaches or suggests a method of treating a patient infected with a virus involving the inhalation of nitrous oxide at normal atmospheric pressure to block virus-host attachment site, to prevent the virus from replication, to reduce viral load and to restore the patient’s system and any of the process steps claimed herein.

A characteristic of a claimed invention is inherent in the prior art only if it necessarily flows from the teachings of the prior art. *In re Oelrich and Divigard*, 212 USPQ 323 (CCPA 1981) (emphasis added). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the alleged inherent characteristic necessarily flows from the teachings of the prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd.Pat.App. & Int. 1990) (emphasis added).

The Examiner has failed to meet this burden because no such evidence or technical reasoning is provided by the Examiner to support the assertion that the inherent characteristic of treating patients infected with a virus necessarily flows from the teachings of the prior art. The Examiner has merely asserted that “the method steps would have directly resulted from use of the device (i.e., upon inhalation of the nitrous oxide, viruses within the patient’s body would be treated). The mechanism by which the virus is treated (i.e., inhaled nitrogen blocking virus-host attachment sites to prevent replication) are inherently carried out by the patient inhaling the

nitrous oxide.”, even though, as Examiner concedes, Watt does not teach treatment of virus of HIV, as recited in claim 15. Again, as above Applicant submits that the Examiner appears to be taking Official Notice improperly and requests that the proper documentation be provided if Examiner maintains this rejections

“[I]nherency is quite immaterial if the record establishes that one of ordinary skill in the art would not appreciate or recognize that inherent result.” *In re Adams*, 148 USPQ 742, 756 (CCPA 1966) (quoting *In re Naylor*, 152 USPQ 106, 108 (CCPA 1966)). For example, where a prior art method of combating microbial infection was also effective to curb appetite, such method of curbing appetite was patentable since it would not have been appreciated or recognized that a method of treating a microbial infection produced the appetite reducing effect. *In re Shetty*, 195 USPQ 753, 756-57 (CCPA 1977). Neither Watt, nor any modification or combination thereof provides a basis to appreciate or recognize that the use of nitrous oxide would regulate the activities described herein such as using nitrous oxide at normal atmospheric pressure to block virus-host attachment site, preventing the virus from replicating, reducing viral load and restoring the patient’s immune system as claimed herein. This result is unexpected and cannot be obvious or inherent. Moreover, none of the references cited in the rejections below, nor any combination thereof provides a basis to appreciate or recognize that the methods of the Watt, or any modification or combination thereof would necessarily result in the claimed invention, and in fact they do not.

The *In re Shetty* court explained that the “Patent Office has failed to show a reasonable expectation, or some predictability, that Brake’s compound would be an effective appetite suppressant if administered in the dosage disclosed by Narayan. The mere hindsight assertion that corresponding dosages render applicant’s method obvious is untenable.” *In re Shetty*, 195 USPQ 753, 757 (CCPA 1977). Here, the Examiner has failed to show a reasonable expectation, or some predictability, that the method disclosed by Watt would in fact be effective in treating a patient infected with a virus and the activities disclosed and claimed by Applicant to be regulated by nitrous oxide particularly when the effects on patients are different, so the hindsight assertion that it would be so cannot be the basis for rejection under 35 U.S.C. §§102 or 103.

Similarly, in *In re Marshall*, 198 USPQ 344 (CCPA 1978), the Court of Customs and Patent Appeals reversed the PTO Board of Appeals and held that claims to a weight control process comprising administering an anesthetic, oxethazaine, to inhibit release of pancreatic

secretory hormones and thereby prevent adsorption of food, were not inherent in claims reciting methods of using oxethazaine to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. In finding that the claimed method to a weight control process was not inherent in the patented method to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome, the *Marshall* Court reasoned that nothing in the cited prior art “suggests taking oxethazaine to lose weight. If anyone ever lost weight following the PDR teachings it was an unrecognized accident.” Here, nothing in Watt, or any modification or combination thereof, suggests that the administration of nitrous oxide to a patient infected with a virus, including HIV, using the method described herein would necessarily regulate all the functions disclosed and claimed in the present application.

Similarly, in *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001), the court found that the method of Rapoport for treating anxiety by administering a certain dosage of a particular drug three times a day was not inherent in the Dement method for treating sleep apnea by administering a larger single dose of the same drug at the time of sleep. The court stated that the method of Rapoport merely disclosed treating anxiety and did not additionally disclose the additional indication of also treating apnea. *Id.* at 1062. The court further stated that Rapoport’s argument was merely based on speculative assumptions regarding treating anxiety at unspecified times versus treating sleep apnea at bedtime. *Id.* The court also reiterated the standards described above, stating that inherency may not be established by probabilities or possibilities and that the mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Id.* at 1063, citing *Cont'l Can Co. USA, Inc. v. Monsanto Co.* 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991); see also *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (“The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency.”).

Thus, where the benefit of an old process would not have been obvious, the new use of a known process is patentable. See *Chisum on Patents* § 1.03 at 1-58; accord *In re Woodruff*, 16 USPQ2d 1934 (Fed. Cir. 1998); *Mehl/Biophile International Corp. v. Milgraum*, 47 USPQ2d 1248 (D.N.J. 1998). See also *Howes v. Great Lakes Press Corp.*, 679 F.2d 1023, 1029, 216 USPQ 1049 (2d Cir. 1982) (holding that “a process or method which involves only a new use of an old material is patentable” and finding the invention patentable where applicant had created a new use of a known process). Even an accidental result does not qualify as an inherent

anticipation result. In *Ebel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923) for example, the Court stated that “accidental results, not intended and not appreciated, do not constitute anticipation.” (citing *Tilghman v. Proctor*, 102 U.S. 707, 711 (1880)).

For the reasons discussed above, neither Watt nor any modification thereof can inherently anticipate the present claims nor is the method in that art inherent in the method of the present application.

In the present case, it is respectfully submitted that one of ordinary skill in the medical arts, in possession of references teaching the inhalator which variably proportions and mixes a plurality of at least three gases as taught and claimed by Watt, would not be led to medically treat a patient infected with a virus, to the extent that he/she is in need of treatment.

The Examiner is requested to consider that the present claims are similar to the claim found to be a patentable new use of an old compound by the Federal Circuit in the recent decision Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368 (Fed. Cir. 2005). The prior art taught certain cosmetic compositions as "suitable for topical application to the hair or skin." Among a group of "skin benefit ingredients," Pereira disclosed the active ingredient which Perricone later claimed as useful to treat skin sunburn. Medicis argued that a claim to treating skin sunburn was inherently anticipated by the prior art teaching of topical application of the same compound to the skin. The Federal Circuit did not agree that the claim to treating sunburn was anticipated because some of the skin surfaces treated following the teachings of the prior art must have been sunburned and so must have been "inherently" helped by application of the old composition. Rather, the Court reasoned:

[T]he issue is not...whether [the prior art] lotion, if applied to skin sunburn would inherently treat that damage, but whether [the prior art] discloses the application of the compound to skin sunburn. It does not. [emphasis in original].... New uses of old products or processes are patentable... In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (principles of inherency do not prohibit a process patent for a new use of an old structure). That principle governs this case as well. ... The disclosed use of [the prior art] lotion, i.e., topical application, does not suggest application of [the prior art] lotion to skin sunburn. ...Because Pereira does not disclose topical application to skin sunburn, this court reverses the [anticipation finding]." 432 F.3d at 1378-1379. [emphasis added]

The court continued: "If [the prior art] did teach sunburn prevention as well as the mechanism behind the prevention, these teachings might suggest that [Patentee's] sunburn

treatment claims would have been obvious. However, those unrealized possibilities do not alter the analysis in this case where [the prior art] does not disclose topical application to skin sunburn." Likewise, in the present case the prior art does not teach or contemplate a method to treat a virus-infected patient.

In fact, in the absence of knowledge of Applicants' invention, no one would administer nitrous oxide to a person infected with a virus, including HIV, expecting that it would be able to treat the infection, much less by blocking virus-host attachment sites and preventing the virus from replicating, and thus reducing viral load and restoring the patient's immune system as recited in claim 15 of the present application. Applicant points out that differences in pathologies treated with the same drug led the Board to reverse an obviousness rejection in *Ex parte Belanoff*, Appeal 2007-11 55 (June 29, 2007).

For these reasons, Applicant submits that claims 15-18 are not obvious over Watt and requests that the rejection as to Watt be withdrawn.

#### **Response to Rejection of Claims 1, 4, 6-9, 11, and 13 under 35 U.S.C. § 103(a), obviousness**

Examiner has rejected claims 1, 4, 6-9, 11, and 13 as allegedly obvious over Gamow et al. (U.S. Pat. No. 4,974,829).

It is the view of the Examiner that as to claims 1, 4, 6, 9, 11, 19, and 20, Gamow discloses a hyperbaric chamber that exposes an individual to surface air at pressures from 0-10 lbs/sq. inches above atmosphere (citing the abstract and col. 4, lines 1-10). Applicant points out that Examiner refers to claims 19 and 20 here, but did not reject claims 19 and 20. However, to ensure completeness, Applicant's arguments below will address 19 and 20 when needed. Applicant notes that claims 19 and 20 have been canceled herein, but their subject matter has been incorporated into the claims from which they depended (described above). Therefore, the rejection (if any) as to claims 19 and 20 is now moot and Applicant requests that the rejection be withdrawn.

It is also the view of the Examiner that the device also monitors vital signs and can be used daily for different amounts of time, etc. The Examiner asserts that the difference between the present claims and Gamow is that Gamow does not disclose that the device is used for treating viruses or HIV. The Examiner then alleges that the method steps would have directly resulted from use of the device (i.e., upon inhalation of the air within the chamber, viruses within

the patient's body would be treated). The Examiner further asserts that the mechanisms by which the virus is treated (i.e., inhaled nitrogen blocking virus-host attachment sites to prevent replication) are inherently carried out by the patient inhaling the surface air.

As to claim 7, Examiner asserts that Gamow is silent as to creating a chart, but provides reasons that the Examiner views rejecting the claims as obvious.

As to claims 8 and 13, the Examiner asserts that the hyperbaric chamber of Gamow is large enough to fit more than one person (citing column 4, lines 25-30). The Examiner then concludes that it would have been obvious to have placed more than one person in the chamber in order to treat more than one person.

Applicant traverses the rejection for the following reasons.

The requirements for an obviousness rejection are outlined above and the arguments and rules presented above as to obviousness and inherent applications apply with equal force here, including Applicants assertion that the Examiner has improperly rejected the claims based on an inherent rejection. However, all points will be addressed in the following arguments.

Gamow teaches and claims a portable, lightweight, collapsible hyperbaric device for training athletes, using greater pressures when at sea level, particularly for those athletes who normally live and train at high altitudes. In fact, the abstract of Gadow, which was cited by the Examiner, states “The chamber is used for endurance conditioning, to improve the athletic performance of people who live at altitudes above sea level”.

Claim 1 as amended recites “a method for increasing a ratio of CD4/CD8 lymphocytes, reducing a viral load and restoring an immune system, including lymph node architecture, of a person infected with at least one virus, including HIV, wherein the person is placed in a hyperbaric chamber and exposed to one or more gases at one or more atmospheric pressures for one or more time-periods, wherein the one or more gases is nitrogen, surface air, an inert gas, nitrous oxide or another anesthetic...” as performed utilizing several steps. Contrary to the assertion of the Examiner, nowhere does Gadow teach or suggest any of these elements, much less all of them, nor do they meet the inherency requirements.

Independent claim 9 as amended recites: “a method for preventing reproduction of a virus wherein a pressurized chamber is used to cause an atom, molecule or compound from gases that fills the chamber, or from within a patient's body, into an attachment site on a cell wall of a living cell or into a receptor unit on the virus, whereby the atom, molecule or compound prevents

the virus from replicating by preventing the virus from attaching to the attachment site of the living cell . . .” comprising the steps of selecting one or more gases to be used inside the chamber, wherein the one or more gases are nitrogen, surface air, an inert gas, nitrous oxide or another anesthetic, selecting one or more pressures to expose the patient to while inside the chamber, selecting one or more time-periods, wherein each time-period is associated with a selected pressure, and, exposing the patient to the one or more selected gases in the chamber at a selected pressure for the associated time-period. Gamow does not teach, suggest, imply or provide motivation as to any of the elements of claim 9, particularly not “a method for preventing reproduction of a virus wherein a pressurized chamber is used to cause an atom, molecule or compound from gases that fills the chamber, or from within a patient's body, into an attachment site on a cell wall of a living cell or into a receptor unit on the virus, whereby the atom, molecule or compound prevents the virus from replicating by preventing the virus from attaching to the attachment site of the living cell . . .”

In order for Gamow to render obvious independent claims 1 and 9 as amended, or any of their dependent claims, it must teach or suggest each and every element of the claims, and it does not because it makes no reference to treating patients infected with a virus, nor does it teach the use of nitrous oxide, nitrogen, surface air (which contains nitrogen), etc. to treat a viral infection, nor does it teach or suggest the use of nitrous oxide to block virus-host attachment sites, nor does it teach or suggest reducing a viral load, nor does it teach or suggest restoring a patient's immune system. Furthermore, not only does it not teach or suggest any of these elements, it does not teach or suggest any of the steps for such treatment as they specifically relate to the treatment of patients infected with a virus recited in independent claims 1 and 9 and their dependent claims. According to MPEP §2143.03, all claim limitations must be considered when an obviousness rejection is being contemplated. Applicant submits that not all claim limitations were considered in the context of the claim.

There would have been no motivation to modify Gamow, which taught pressure chambers for enhancing athletic performance, not treating virus-infected patients as claimed herein, and there would have been no reasonable expectation of success because of the unpredictability of the discovery and treatment claimed herein. Gamow did not teach anything closely related to what is presently claimed, and even a hindsight analysis could not lead to the use of Gamow. Gamow did not provide such motivation and the Examiner has provided no

reasoning or evidence that one of ordinary skill in the art would have modified Gamow to treat virus-infected patients, as disclosed and recited in the present application. As discussed in *KSR*, treatments such as these in the pharmaceutical and biological arts are highly unpredictable and hindsight bias and ex post reasoning in the face of Applicant's success is not allowed. Applicant submits that based on what was known at the time of this invention, it is not possible for Gamow to render independent claims 1 and 9 as amended and their dependent claims obvious. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007)". Applicant submits that even if there were a motivation to modify Gamow or there were teachings or suggestions to do so, it would have been unpredictable to do so because there was no evidence that the device or an intended use was even related to treating a patient with a virus, and even if it were suggested there would have been no way of predicting success.

Applicant also submits that Examiner's use of an inherent rejection is improper for the reasons described above and requests that it be withdrawn. However, even if the rejection were proper, Applicant submits that the claims are not obvious over Gamow for the following reasons.

Applicant asserts that, based on the statements by the Examiner, Examiners appears to be either relying on common knowledge or is taking Official Notice and Applicant submits that this has not been properly done. Furthermore, an Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. See *KSR Int'l Co.*, 550 U.S. \_\_\_ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)); *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). Conclusions of obviousness must be based on facts, not generality. *In re Warner*, 379 F.2d 1011, 1017 (C.C.P.A. 1967); *In re Freed*, 425 F.2d 785, 787 (C.C.P.A. 1970). Applicant submits that neither has been done here.

MPEP § 2112 explains that the "express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102," but MPEP § 2112(IV-V) requires that the Examiner must provide a rationale for rejection based on an "inherent property." Applicants respectfully submit that in the present Office Action, the Examiner has not met this burden. The Examiner has not provided evidence or reasoning

tending to show that the missing claimed method of use is necessarily present in the disclosure of the cited reference, either alone or in combination. The extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. The present independent claims (1 and 9) recite a method of treating a patient infected with a virus involving the inhalation of nitrogen or nitrous oxide at normal atmospheric pressure to block virus-host attachment site, to prevent the virus from replication, to reduce viral load and to restore the patient's system, as well as a method to specifically prevent reproduction of a virus (claim 9). These methods are not inherent in the method disclosed by the cited reference. The Examiner has not provided evidence that one of ordinary skill in the art would have recognized that the disclosure of Gamow teaches or suggests a method of treating a patient infected with a virus involving the inhalation of nitrogen or nitrous oxide at normal atmospheric pressure to block virus-host attachment site, to prevent the virus from replication, to reduce viral load and to restore the patient's system and any of the process steps claimed herein.

A characteristic of a claimed invention is inherent in the prior art only if it necessarily flows from the teachings of the prior art. In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the alleged inherent characteristic necessarily flows from the teachings of the prior art.

No reasoning is provided by the Examiner to support the assertion that the inherent characteristic of treating patients infected with a virus necessarily flows from the teachings of the prior art. The Examiner has merely asserted that “the method steps would have directly resulted from use of the device (i.e., upon inhalation of the nitrogen or nitrous oxide, viruses within the patient's body would be treated). The mechanism by which the virus is treated (i.e., inhaled nitrogen blocking virus-host attachment sites to prevent replication) are inherently carried out by the patient inhaling the nitrous oxide.”, even though, as Examiner concedes, Gamow does not teach treatment of virus of HIV. Again, as above Applicant submits that the Examiner appears to be taking Official Notice improperly and requests that the proper documentation be provided if Examiner maintains this rejection.

One of ordinary skill in the art would not appreciate or recognize the inherent result suggested by the Examiner and thus the test required by *In re Adams* and *In re Shetty* would not

be satisfied. Neither Gamow, nor any modification or combination thereof provides a basis to appreciate or recognize that the use of nitrogen or nitrous oxide would regulate the activities described herein such as using nitrogen or nitrous oxide at normal atmospheric pressure to block virus-host attachment site, preventing the virus from replicating, reducing viral load and restoring the patient's immune system as claimed herein. This result is unexpected and cannot be obvious or inherent. Additionally, *In re Shetty* requires that there be a reasonable expectation, or some predictability, and that is not provided here. Here, the Examiner has failed to show a reasonable expectation, or some predictability, that the method disclosed by Gamow would in fact be effective in treating a patient infected with a virus and the activities disclosed and claimed by Applicant to be regulated, particularly when the effects on patients are different, so a hindsight assertion that it would be so cannot be the basis for rejection under 35 U.S.C. §§102 or 103.

The present rejection further does not meet the requirements of *In re Marshall* (see above). Here, nothing in Gamow, or any modification or combination thereof, suggests that the administration of nitrous oxide, or the gases claimed herein, to a patient infected with a virus, including HIV, using the method described herein would necessarily regulate all the functions disclosed and claimed in the present application.

As required in *Rapoport v. Dement* (see above), an argument that is merely based on speculative assumptions is not valid. There is no evidence that the Examiner's assertions are more than probabilities or assertions in this case.

For the reasons discussed above, neither Gamow nor any modification thereof can inherently render the present claims obvious or anticipated, nor is the method in that art inherent in the method of the present application.

Applicant submits that for the reasons provided above, independent claims 1 and 9 as amended and dependent claims 4, 6-8, 11, and 13, as well as the subject matter of canceled claims 19 and 20 (their subject matter has been incorporated into the claims from which they depended), are not obvious over Gamow and requests that the rejection as to these claims be withdrawn. Applicant further submits that the same arguments apply to newly added claims 21 and 22.

**Response to Rejection of Claims 15-18 under 35 U.S.C. § 103(a), obviousness**

Examiner has rejected claims 15-18 as allegedly obvious over Duke University (WO 96/31217; Stamler et al.). Examiner asserts that, as to claims 15 and 16, Duke discloses a method for treating patients infected with a virus, including HIV (citing page 4, 3<sup>rd</sup> full paragraph), involving the inhalation of **nitric** oxide (NO) at normal atmosphere pressure (citing page 6, 2<sup>nd</sup> full paragraph, page 15, last paragraph, page 18, 3<sup>rd</sup> full paragraph, page 20, 2<sup>nd</sup> full paragraph, and claims 1-3. The Examiner goes on to assert that the mechanisms would be inherent and that other aspects of the claims would be obvious. As to claims 17 and 18, Examiner admits that Duke does not disclose that NO is provided at a concentration of 5% or more or even that different percentages are taught, but that other aspects of the claims would have been obvious.

Applicant traverses for the following reasons, noting that the requirements for an obviousness rejection are detailed above.

Regarding the rejection of “independent” claim 15 and its dependent claims 16-18, Applicant points out that each and every element of the claims must be taught or suggested by the prior art, and Applicant asserts that this reference does not.

First, Applicant would like to point out that the compound used by Duke, “nitric oxide” (NO), is not the same as the compound nitrous oxide which is recited in claim 15. In fact, the compounds do not function in the same manner (i.e., different mechanisms of action) and, therefore, Duke is not even applicable or relevant to this application. Because of the different mechanisms of action, Duke would teach away from the present application. For this reason, the rejection as to Duke should be withdrawn. Further reasons are described below.

Although both NO (used by Duke) and nitrous oxide contain a nitrogen atom, there is no overlap in their direct mechanisms of action as evidenced by the teachings in Duke, the present application, the references cited in both, and the references cited by the Examiner. Even basic and scientific dictionary definitions clearly recite totally distinct definitions and functions for nitric oxide (NO) and nitrous oxide. NO is defined as an endogenous signaling molecule that regulates vasodilation and nitrous oxide is referred to as an anesthetic (and is not an endogenous molecule in animals). Only the unexpected discovery described herein discloses that nitrous oxide effects the ability of viruses to attach to viral receptor sites, which in turn effects viral replication.

Applicant further points out that, although the present application recites nitrous oxide and discusses nitrogen gas in other parts of the application, no reference is made in the present application to nitric oxide, because it was known to behave differently than nitrous oxide (an anesthetic) or nitrogen. In fact, the Nobel Prize in Physiology or Medicine for 1998 was awarded to Robert Furchtgott, Louis Ignarro, and Ferid Murad for their discoveries of the 1970s and 1980s concerning " nitric oxide as a signalling molecule in the cardiovascular system". Today, the regulation of the nitric oxide signaling pathway is a medical target to regulate blood flow, and is in fact the target of **Viagra™**. The Duke patent publication cited by the Examiner is one of many by the Duke group where they utilize nitric oxide as a signaling molecule, another distinction from nitrous oxide recited in the present claims. Applicant points out that nowhere in the Duke reference is anything cited that appears to be similar to the present application because it was known that NO, as used in the Duke application, was an endogenous molecule, and in fact the Duke publication discusses in vivo production of NO, the role of NO in specifically binding to proteins (nitrosylation) in the NO signal transduction pathway, as well as other compounds that can serve as NO donors, and how the signal transduction pathway of NO is regulated. None of those compounds are the gases recited in the present application because none of the gases presently claimed, in this case nitrous oxide in claims 15-18, perform the functions described in Duke, and vice-versa.

Additionally, one of the references cited in the Duke publication asserted by the Examiner, Kowaluk et al., J. Pharmacol. Exp. Therap., 1990, 255:1256-1264 (cited at page 7 of Duke), explicitly describes NO as a potent vasodilator and further describes its signaling pathway (see abstract of Kowaluk). The lack of referral to NO in any of the other references cited by the Examiner, as well as a lack of reference to NO or its signaling pathways in the present application or other references using hyperbaric chambers cited by the Examiner, further highlights the distinct and separate mechanism of NO and nitrous oxide.

Even if NO, as used in Duke, and nitrous oxide, as recited in claim 15, were similar, there was no reference in Duke to use NO or nitrous oxide as claimed in the present application. There was no teaching or suggestion to provide a motivation to use NO or nitrous oxide, because nitrous oxide and NO have different functions. The functions are so different that there would have been no motivation to modify Duke to use NO in the method of the present invention, and there was no teaching or suggestion in Duke as to the other elements of claims 15-18, as

admitted by the Examiner. Even if they were similar, there is no teaching or suggestion in Duke to use NO to practice the present invention, and the Examiner has not provided the reasoning and evidence that such a motivation would have existed. Furthermore, there is no evidence in Duke, nor was any provided by the Examiner, that there would have been predictability or a reasonable expectation of success. Again, as asserted above, the inherent rejection is improper here and should be withdrawn. Moreover, as indicated here, the molecules function differently and inherency cannot exist, and would not be a successful rejection, even if used in an anticipation rejection.

Duke teaches NO, delivering, releasing and transferring compounds of NO such as S-nitrosothiols (all used in regulating the nitric oxide signalling pathway; claims 1 and 4), and regulating NO synthase (claims 18 and 21). Even the paragraph cited by the Examiner at page 6 of Duke describes how NO is regulated and is a moiety for attachment to a protein as an NO adduct and the types of molecules involved with releasing, delivering, or transferring NO to a protein. Other types of NO adducts are also described at pages 12-15 of Duke, none of which are nitrous oxide (recited in claim 15) because nitrous oxide does not function as such and does not have an involvement in the NO regulatory/signalling pathway. The proteins of Duke are not the virus-attachment sites blocked by nitrous oxide as described and claimed in the present application.

Additionally, for a reference to render a claim obvious, it must teach each and every element of the claim, and Duke does not. According to MPEP §2143.03, all claim limitations must be considered when an obviousness rejection is being contemplated. For example, claim 15 recites “A method for the treatment of patients infected with a virus, including HIV, involving the inhalation of nitrous oxide at normal atmospheric pressure wherein inhaled nitrogen blocks virus-host attachment sites and prevents the virus from replicating thereby reducing viral load and restoring a patient's immune system . . . “ the method comprising several steps (emphasis added). Duke does not teach or suggest nitrous oxide, blocking virus-host attachment sites, reducing viral load, and restoring a patients' immune system, as recited in claim 15, nor does it recite the steps with which to perform this method, as recited in claim 15 and dependent claims 16-18. Furthermore, as described above the mechanisms of action of NO and nitrous oxide are different.

Because one of ordinary skill in the art would know the differences in function and mechanism of action between NO, as taught by Duke, and nitrous oxide, as claimed herein, there would have been no motivation to modify Duke to arrive at the present invention as claimed. Additionally, there would have been no expectation of success, much less a reasonable expectation of success. In fact, Applicant submits that the teachings of Duke and what was known in the art teaches away from the present invention, at least as far as any motivation to modify Duke.

As discussed in *KSR*, treatments such as these in the pharmaceutical and biological arts are highly unpredictable and hindsight bias and *ex post* reasoning in the face of Applicant's success is not allowed. Applicant submits that, based on what was known at the time of this invention, it is not possible for Duke to render claims 15-18 obvious. There would have been no motivation to modify Duke, which taught nitric oxide (NO) and its signal transduction pathway and regulators, there would have been no reasonable expectation of success because of the unpredictability of the treatment claimed herein, Duke did not teach, suggest, or even contemplate what is presently claimed, and even a hindsight analysis could not lead to modifying Duke to practice the present invention, because it would not work.

Furthermore, as discussed above, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007)". Applicant submits that even if there were a motivation to modify Duke or there were teachings or suggestions to do so, it would have been unpredictable to do so because of the fact that NO does not act via the same mechanism as does nitrous oxide, and even if it were suggested there would have been no way of predicting success, because it would not have been a reasonable expectation. If fact it would teach away.

As reasoned above, Examiner appears to be either relying on common knowledge or is taking Official Notice and Applicant submits that this has not been properly done. Examiner must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding and Examiner must provide a rationale for rejection based on an "inherent property." Applicants respectfully submit that in the present Office Action, the Examiner has not met this burden. This is because the Examiner has not provided evidence or reasoning tending to

show that the missing claimed method of use is necessarily present in the disclosure of the cited reference, either alone or in combination. The extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. The present claims recite a method of treating a patient infected with a virus involving the inhalation of nitrous oxide at normal atmospheric pressure to block virus-host attachment site, to prevent the virus from replication, to reduce viral load and to restore the patient's system, as well as a method to specifically prevent reproduction of a virus. These methods are not inherent in the method disclosed by the cited reference because of the difference in the compounds being used.

A characteristic of a claimed invention is inherent in the prior art only if it necessarily flows from the teachings of the prior art. In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the alleged inherent characteristic necessarily flows from the teachings of the prior art.

The Examiner has failed to meet this burden because no such evidence or technical reasoning is provided by the Examiner to support the assertion that the inherent characteristic of treating patients infected with a virus necessarily flows from the teachings of the prior art. In fact, as described above, NO and nitrous oxide have different mechanisms of action.

Applicant asserts that one of ordinary skill in the art would not appreciate or recognize the inherent result suggested by the Examiner and thus tests required by *In re Adams* and *In re Shetty* would not be met. Neither Duke, nor any modification or combination thereof provides a basis to appreciate or recognize that the use of nitrous oxide would regulate the activities described herein such as using nitrous oxide at normal atmospheric pressure to block virus-host attachment site, preventing the virus from replicating, reducing viral load and restoring the patient's immune system as claimed herein. This result is unexpected and cannot be obvious or inherent, particularly since the mechanisms of action of NO and nitrous oxide are different. Moreover, none of the references cited in the rejections below, nor any combination thereof provides a basis to appreciate or recognize that the methods of the Duke, or any modification or combination thereof would necessarily result in the claimed invention, and in fact they do not. Additionally, *In re Shetty* requires that there be a reasonable expectation, or some predictability, and that is not provided here. Here, the Examiner has failed to show a reasonable expectation, or

some predictability, that the method disclosed by Duke would in fact be effective in treating a patient infected with a virus and the activities disclosed and claimed by Applicant to be regulated, particularly when the effects on patients are different, so a hindsight assertion that it would be so cannot be the basis for rejection under 35 U.S.C. §§102 or 103.

As required in *Rapoport v. Dement*, an argument that is merely based on speculative assumptions is not valid. There is no evidence that the Examiner's assertions are more than probabilities or assertions in this case.

For the reasons discussed above, neither Duke nor any modification thereof can inherently render the present claims obvious or anticipated, nor is the method in that art inherent in the method of the present application.

Applicant submits that for the reasons provided above, claims 15-18 are not obvious over Duke and requests that the rejection as to these claims be withdrawn.

#### **Response to Rejection of Claims 3, 5, 12, and 14 under 35 U.S.C. § 103(a), obviousness**

Examiner has rejected claims 3, 5, 12, and 14 as allegedly obvious over Gamow, as applied to claims 1, 4, 6-9, 11, and 13 above, and further in view of Lasley (U.S. Pat. No. 4,448,189).

Applicant is confused by the wording of the rejection and points out that if the Examiner is not rejecting claim 1 here, from which rejected claims 3, 5, 12, and 14 depend, then the rejection fails. As stated in MPEP § 2143.03: "If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)." If this is what Examiner is suggesting then Applicant submits that the rejection fails and requests that the rejection be withdrawn as to all claims. However, Applicant will respond to the rejection in case the Examiner meant to reject claim 1 as well.

Examiner admits that as to claims 3, 5, and 12, Gamow does not disclose the claimed pressures, but that Lasley discloses a hyperbaric chamber that exposes patients to pressures of 30-70 psi, which overlaps the claimed range. The Examiner then states that "it would have been obvious to one of ordinary skill in the art at the time of the invention to have exposed patients in the device of Gamow et al. to pressures of 30-70 psi as taught by Lasley in order to treat a given condition and to suit an individuals needs". The Examiner further states that it appears as though

the device of Gamow would work equally well if the patient were exposed to pressures of 30-70 psi.

As to claim 14, Examiner asserts that to the extent, if any, that Gamow does not disclose decompression intervals and choosing a decompression time off of a standard decompression table, Lasley is cited to show that it is well known to cycle patients through periods of decompression during hyperbaric therapy. Examiner then states that it would have been obvious to one of ordinary skill in the art to have chosen decompression tables from a standard table to ensure that the patient is not hurt and that such tables are well known, and further that it appears that the device of Gamow would perform equally well if a patient were cycled through decompression.

Applicant submits that the arguments provided above as to Gamow apply with equal force here and that Gamow cannot render the claims obvious, alone or in combination with another reference such as Lasley.

For a combination of references to be used, each reference of the combination must stand up to arguments or the entire rejection fails.

Applicant points out that there must be some motivation to combine references in an obviousness rejection and that there must be some reasonable expectation of success. Applicant asserts that there is nothing in either Gamow or Lasley that would provide the motivation to combine the references, and further that the Examiner has provided no reasoning supported by evidence to explain such motivation. Additionally, even if there were motivation, there would be no reasonable expectation of success, because even if the two references were combined, the result would not be the present invention. As described above, Gamow teaches and claims a lightweight portable collapsible chamber for training athletes. There is nothing in Gamow or Lasley that would provide the motivation, or reasonable expectation of success, to combine the references to arrive at the present invention, because the resulting combination would be a chamber for training athletes where the athletes could undergo decompression. In fact, Lasley merely teaches fluidic valves for use with a hyperbaric chamber to regulate oxygen flow. Lasley does not teach or suggest using other gases nor does it teach treating patients with viral infections.

A chamber for training athletes where there can be decompression (which is the resulting combination of Gamow and Lasley) is not the present invention as claimed, which instead

encompasses “A method for increasing a ratio of CD4/CD8 lymphocytes, reducing a viral load and restoring an immune system, including lymph node architecture, of a person infected with at least one virus, including HIV, wherein the person is placed in a hyperbaric chamber and exposed to one or more gases at one or more atmospheric pressures for one or more time-periods, wherein the one or more gases is nitrogen, surface air, an inert gas, nitrous oxide or another anesthetic, and the method comprises selecting the one or more gases to be used in the hyperbaric chamber; selecting the one or more pressures to be used in the hyperbaric chamber; selecting the one or more time-periods that the patient is exposed to the selected gas(es) and pressure(s) while in the hyperbaric chamber; placing the patient in, or having the patient enter, the hyperbaric chamber wherein monitoring of the patient's vital signs may optionally be provided; and, exposing the patient to the selected one or more gases, at the selected one or more pressures for the selected one or more time-periods, and as to claim 3, wherein the one or more pressures selected are at least one atmosphere. Clearly, even if the two references were combined, there would have been no expectation of success.

Applicant submits that even if there were a motivation to combine Gamow and Lasley or there were teachings or suggestions to do so, it would have been unpredictable to do so because there was no evidence that the device or an intended use was even related to treating a patient with a virus, and even if it were suggested there would have been no way of predicting success. Even *KSR* requires predictability.

For these reasons, neither Gamow nor Lasley, even when combined, teach, suggest, or imply all of the elements of the rejected claims. This is further support for the argument that there would be no motivation to combine or modify the references, nor would there be a reasonable expectation of success.

Applicant submits that for the reasons described above, the claims are not obvious over Gamow and Lasley and requests that the rejection be withdrawn.

#### **Response to Rejection of Claims 1, 3-9, and 11-14 under 35 U.S.C. § 103(a), obviousness**

Examiner has rejected claims 1, 3-9, and 11-14 as allegedly obvious over Duke in view of Reillo et al. (J. Assoc. Nurses in AIDS Jan-Feb. 1996) and Lasley.

Examiner asserts that regarding claims 1, 4, 9, and 11: Duke discloses a method of treating HIV involving inhaling NO, but admits that Duke is silent as to a hyperbaric chamber;

Reillo discloses, in a method for treating HIV, placing a patient in a hyperbaric chamber for inhalation therapy. The Examiner then concludes that it would have been obvious to have had the patient of Duke inhale NO while in a hyperbaric chamber as taught by Reillo in order to provide the well known benefits of treating HIV patients with gas at an elevated pressure in a hyperbaric chamber. The Examiner further asserts that “it appears as though the method of Duke would work equally well if the gas were supplied at an elevated pressure within a hyperbaric chamber inasmuch as a therapeutically effective amount were being delivered (see discussion above with respect to the concentration of NO being greater than 5%).” The Examiner also asserts that individually claims mechanisms by which the virus is treated (i.e., reducing viral load, increasing CD/4/CD8 lymphocytes, blocking virus-host attachment sites to prevent replication, etc.) are inherently carried out by the patient inhaling the nitric oxide.

Examiner admits that Reillo is silent as to selecting one or more time periods for exposing the patients to selected gases and pressure, but states that Lasley discloses a hyperbaric chamber used for therapy that allows a physician to select a desired prescribed pressure, time, etc. The Examiner then asserts that it would have been obvious to have provided the NO in the modified Duke reference with the hyperbaric chamber disclosed by Lasley in order to allow a physician to select a desired time and pressure, etc.

Regarding claims 3, 5, and 12, Examiner asserts that Lasley discloses pressures of 30-70 psi, which overlap the claimed ranges. Examiner concludes that it would have been obvious to have provided the NO in the modified Duke device at a pressure 30-70 and that these pressures are well known and that it appears as though the modified Duke reference would perform equally well if the NO were provided at 30-70 psi.

Regarding claim 6, Examiner asserts that the modified Duke reference discloses that a treatment is repeated (citing page 20), but admits that Duke is silent as to the exposure being repeated daily for 3-21 days. The Examiner then concludes that absent a critical teaching and/or showing of unexpected results, it is her position that it is an obvious design consideration to expose the patient in the modified Duke reference to NO daily for 3-21 days.

The Examiner provides similar types of rejections as to dependent claims 8, 13, and 14. Applicant traverses the rejection for the following reasons.

The failings of Duke were described above as to its use as a prior art reference, including the inappropriate comparison of NO to the gases claimed in the present application and the fact

that nitrous oxide and nitrogen (which is also a component of air) as claimed work via totally distinct cellular mechanisms than does the NO of Duke, and Applicant submits that Reillo does not correct those deficiencies. Reillo in fact teaches hyperbaric chamber therapy using 100% oxygen and further teaches that the subjects are being treated with anti-oxidant therapy. The present application does not claim the use of 100% oxygen as taught by Reillo, but instead recites the use of one or more gases at one or more atmospheric pressures for one or more time-periods, and that the one or more gases are nitrogen, surface air, an inert gas, nitrous oxide or another anesthetic. Regarding varied pressures, the use of 100% oxygen as taught by Reillo, would be deadly if used at a psi of about 70, as suggested by the Examiner. Additionally, the present application shows unexpectedly that oxygen does not even work as well as surface air or surface air plus nitrous oxide. As described above, Lasley merely teaches fluidic valves for use with a hyperbaric chamber to regulate oxygen flow. Lasley does not teach or suggest using other gases nor does it teach treating patients with viral infections.

Because it was known that NO, as used in Duke, does not work via the same mechanism as nitrous oxide, nitrogen, etc. (as used and claimed in the present application), one of ordinary skill in the art would not have been motivated to combine Duke, Reillo, and Lasley because they would have known that the resulting combination does not arrive at the present invention. Although there may have been motivation to find a way to make Duke better by using a hyperbaric chamber, the result is still not the same as the present invention because the mechanisms of action are not inherently the same.

Additionally, the references do not teach, suggest, or even contemplate each and every element of the rejected claims, even the base claims, as discussed above in detail. Claim 1 encompasses a method for increasing a ratio of CD4/CD8 lymphocytes, reducing a viral load and restoring an immune system, including lymph node architecture, of a person infected with at least one virus, including HIV, wherein the person is placed in a hyperbaric chamber and exposed to one or more gases at one or more atmospheric pressures for one or more time-periods, wherein the one or more gases is nitrogen, surface air, an inert gas, nitrous oxide or another anesthetic, using the steps of selecting the one or more gases to be used in the hyperbaric chamber; selecting the one or more pressures to be used in the hyperbaric chamber; selecting the one or more time-periods that the patient is exposed to the selected gas(es) and pressure(s) while in the hyperbaric chamber; placing the patient in, or having the patient enter,

the hyperbaric chamber wherein monitoring of the patient's vital signs may optionally be provided; and, exposing the patient to the selected one or more gases, at the selected one or more pressures for the selected one or more time-periods. The gist of independent claim 9 is similar to claim 1, although it concentrates more on inhibiting the virus as opposed to treatment. That is, claim 9 encompasses a method for preventing reproduction of a virus using a pressurized chamber to cause an atom, molecule or compound from gases that fills the chamber, or from within a patient's body, into an attachment site on a cell wall of a living cell or into a receptor unit on the virus, whereby the atom, molecule or compound prevents the virus from replicating by preventing the virus from attaching to the attachment site of the living cell.

For the reasons described above, the combination of Duke, Reillo, and Lasley does not result in the present invention because the compounds act via different mechanisms, provides no motivation or teachings to suggest the present invention, and there were none in the art to suggest such, particularly since the mechanism of action of NO as used in Duke was known to be different than what is presently claimed. Thus, there was no predictability of success. Therefore, this combination cannot render the present claims obvious and Applicant requests that the rejection as to these claims be withdrawn.

#### **Response to Rejection of Claims 19 and 20 under 35 U.S.C. § 103(a), obviousness**

Examiner has rejected claims 19 and 20 as allegedly obvious over Duke, Reillo, and Lasley as applied to claims 1, 3-9, and 11-14 above, and further in view of Gamow. Examiner asserts that the modified Duke reference is silent as to supplying the gas at atmospheric pressure. However, Gamow discloses a hyperbaric chamber that exposes a patient to a gas at atmospheric pressure (citing the abstract). The Examiner then concludes that it would have been obvious to one of ordinary skill in the art to have provided the pressure of NO in the modified Duke reference at atmospheric pressure as taught by Gamow, depending on the desired treatment and pressures need to effectively treat the patient. The Examiner further speculates that it appears as though the modified Duke reference would perform equally well with the pressure provided at atmospheric pressure in as much as an effective amount of NO was provided to the patient for inhalation.

Applicant is again confused by the way the rejection is stated because the independent claims from which claims 19 and 20 depend are not specifically rejected here. As stated in

MPEP § 2143.03: “If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).” If this is what Examiner is suggesting then Applicant submits that the rejection fails and requests that the rejection be withdrawn. However, Applicant will respond to the rejection in case the Examiner meant to reject the independent claims as well.

Applicant points out that claims 19 and 20 are canceled herein, but their subject matter has been incorporated into independent claims 1 and 9 respectively, the claims from which they depend, so Applicant will address the rejection as to claims 1 and 9.

Applicant traverses for the following reasons.

Duke, Reillo, Lasley, and Gamow have each been discussed above and the explanations and arguments against these references apply with equal force here, including as to their combination. Each and every element of claim must be taught or suggested by the prior art, and these references do not. Contrary to the assertion of the Examiner, neither Duke, Reillo, Lasley, and Gamow teach, suggest, or even contemplate each and every element of independent claim 1, as amended, and its dependent claim. That is, they do not conform to the multiple criteria recited above for making an obviousness rejection. Additionally, in several instances the Examiner makes assertions regarding knowledge in the art, but does not cite such art to substantiate the assertion. Such documentation is required and if another Office Action is rendered it should contain references to support assertions of what is known in the art to support such Official Notice.

The real question regarding obviousness should be “would one of ordinary skill in the art want to, or be motivated to modify or combine the HIV treatment of Reillo, which appears to successfully use hyperbaric oxygenation (and no other gases), with the HIV treatment of Duke which appears to be successful without hyperbaric oxygenation and uses a gas (NO) which works by a mechanism different than that of Reillo (or the compounds of the present invention), to arrive at the present invention which uses, *inter alia*, nitrogen gases which were found by the Applicant to be unexpectedly more effective than oxygen alone?”. This question can be expanded by adding the other two cited references. The answer is still no because NO, as taught by Duke, was known to act via a different mechanism than the molecules and gases taught and claimed in the present application. This question does not even contemplate the additional elements recited in claim 1 that are not taught or suggested by any of the four cited references.

However, when referring to the important recitation of the use of nitrogen and nitrous oxide as recited in amended claim 1, these references do not teach, suggest, or even contemplate its use, nor would there have been a reasonable or predictable expectation of success as is required by law (MPEP 2143.02; *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976; *Ex parte Atkinson and Benedict*, BPAI Appeal No. 2007-3900, 12/18/07; *Ex parte Rathman*, BPAI Appeal No. 2007-4156, 12/11/07). Furthermore, the Examiner provides no objective evidence to support the assertion that it would be obvious to use other gases, the nitrogen ones in particular, as is required. (*KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007); *Ex parte Penhasi*, BPAI Appeal No. 2007-2534 (12/13/07); *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, 1/14/08). There was nothing in those references, or any other art to which the Examiner may have been trying to take notice of, which suggests that using a different gas such as nitrogen or nitrous oxide, as is recited in the present claims, would be effective, much less more effective than hyperbaric oxygenation. Even if the references were combined, the result is not the present invention.

Another difference between Duke/Reillo/Lasley/Gamow and what is presently claimed is that Duke and Reillo only teach treating HIV, while the present application is not limited to HIV. They do not teach or suggest treating other viruses, as is recited in claim 1, as well as in independent claim 9. Additionally, Duke/Reillo/Lasley/Gamow are not enabling references even if they did suggest treating other viruses, as is taught and claimed in the present application.

Furthermore, the data provided in the present application point to a different conclusion than that forwarded by the Examiner regarding obviousness. For example, the data demonstrate that nitrogen not only worked, but that it was much more effective than hyperbaric oxygenation in treating virus. For example, one element recited by claim 1 is “restoring lymph node architecture”, which is not taught or suggested by Duke/Reillo/Lasley/Gamow. It can be seen in Figure 5B that nitrogen treatment was very effective in restoring lymph node architecture. The data from these experiments is also provided in graphic from in Figure 6. There it can be seen that, not only is nitrogen effective, it is much more effective than hyperbaric oxygenation (see also paragraphs 0051 to 0054 of this application as published- US 2005/0056285).

Examiner refers to inherent mechanisms, which Applicant submits is an improper use of inherency as described in detail above and which Applicant requests be withdrawn. However, for the reasons described above, Applicant asserts that an inherent rejection still fails because the

use of NO, as taught by Duke and suggested by the Examiner, is not relevant because it is a different type of molecule than the ones cited herein and is instead a signalling molecule, and in fact works via different mechanisms. Applicant submits that this statement by the Examiner regarding “inherently” should be withdrawn unless art is cited to support it as is required for an obviousness rejection.

Additionally, Applicant points out that claims 1 and 9 not only recite “increasing a ratio of CD4/CD8 lymphocytes” and “reducing a viral load”, they also recite “restoring an immune system, including lymph node architecture”, which are not taught or suggested by the art, particularly not Reillo. The Examiner did not address this aspect of the claim at all. Regardless, neither Duke/Reillo/Lasley/Gamow, alone or in combination teach or suggest “restoring an immune system, including lymph node architecture”, therefore, they do not render this element of claim 1 obvious, and therefore cannot render claim 1 obvious.

Therefore, there would no reason or motivation to combine Duke/Reillo/Lasley/Gamow or a reasonable or predictable expectation of success as to arriving at claims 1 or 9, much less their dependent claims, as well as newly added claims 21 and 22, because they teach different amounts of pressure than the claims as recited and do not suggest that nitrogen or other gases could be used, much less that they would work better than oxygen, as used and taught by Reillo. There would be no motivation to vary the pressure as asserted by the Examiner, because Duke and Reillo were successful in their results and neither suggested that varying pressure would perhaps provide better results.

Regarding the rejection of the dependent claims, Applicant asserts that the arguments provided for amended independent claims 1 and 9 apply with equal force here. Additionally, the Examiner must do more than merely state that something is “inherent” for use in an obviousness rejection. The examiner must provide evidence that one of ordinary skill in the art would have varied the pressure at ranges greater than one atmosphere and articulate a sufficient reason as to why one skilled in the art would have modified the art and arrived at the presently claimed subject matter (*Ex Parte Penhasi*; (*Ex parte So and Thomas*, BPAI, 2007-3967; January 4, 2008). A hyperbaric chamber does not have to necessarily be used under pressure and can be used as a means to regulate the air and gases which a patient is exposed to.

In fact, based on their data and discussion Reillo would suggest that pressure is needed based on the fact that they studied and used only hyperbaric oxygen, had success with oxygen

under pressure, did not discuss other pressures or gases, which in fact would teach away from using only one atmospheric pressure as claimed herein, as well as teach away from using other gases. Therefore, neither Duke/Reillo/Lasley/Gamow, teach or suggest each and every limitation of the rejected claims. Furthermore, even if they did, they provided no motivation or suggestion to modify or combine the references to arrive at the present invention, nor was there a predictable or reasonable expectation of success. In fact, even if the teachings of Duke/Reillo/Lasley/Gamow were combined, they do not result in the present invention as recited.

Presuming arguendo that the references show the elements or concepts urged by the examiner, the examiner has presented no line of reasoning, and we know of none, as to why the artisan viewing only the collective teachings of the references would have found it obvious to selectively pick and choose various elements and/or concepts from the several references relied upon to arrive at the claimed invention. *Ex Parte Clapp*, 227 USPQ 972 (PTO Bd App. 1985); *In Re Horn*, 203 USPQ 969 (CCPA 1979). More recently the Board held that, regarding hindsight analysis in an obviousness rejection “there is nothing in the applied references which would have motivated an artisan to select the particular ingredient and then use the resulting composition” (*Ex parte So and Thomas*, BPAI, 2007-3967; January 4, 2008). The collection of references cited by the Examiner supports the inescapable conclusion that the Examiner has pieced the references together to support a rejection on the basis of hindsight.

As the Federal Circuit has held numerous times, such a hindsight analysis is impermissible -- instead, the Examiner must show suggestions, explicit or otherwise, that would compel one of ordinary skill to combine the cited references in order to make and use the claimed invention. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) (“When prior art references require selective combination by the [fact-finder] to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.”); *Fine*, 5 USPQ2d at 1600 (“One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”); *In re Pleuddemann*, 910 F.2d 823, 828 (Fed. Cir. 1990) (noting that use of an applicant’s specification as though it were prior art to support an obviousness determination is legal error); *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (holding that both the suggestion to combine references, and a reasonable expectation of success

in making the claimed invention, “must be founded in the prior art, not in the applicant’s disclosure.”). The Board has also provided the same mandate on this issue:

“it is impermissible to use the claimed invention as an instruction manual or “template” to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious . . . a rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis.”

*Ex parte Haymond*, 41 USPQ2d 1217, 1220 (Bd. Pat. App. Int. 1996). Thus, the use of hindsight analysis in the present case is impermissible and cannot be used to attempt to establish a *prima facie* case of obviousness.

Regarding the rejection of “independent” claim 9, Applicant asserts that the applicable arguments supplied above as to the rejection of claim 1 apply with equal force. The Examiner refers to the rejection of claim 1 as the sole reason for rejection of claim 9, but Applicant points out that totally different elements are recited in claim 9, relative to claim 1. The preamble of independent claim 9, as amended herein, recites:

A method for preventing reproduction of a virus wherein a pressurized chamber is used to cause an atom, molecule or compound from gases that fills the chamber, or from within a patient's body, into an attachment site on a cell wall of a living cell or into a receptor unit on the virus, whereby the atom, molecule or compound prevents the virus from replicating by preventing the virus from attaching to the attachment site of the living cell, the method comprising the steps of:

(emphasis added)

The remainder of amended independent claim 9 recites the steps of the process, the use of various gases, etc., as recited in claim 1.

Applicant points out that the elements underlined above in claim 9 are not taught or suggested by Duke/Reillo/Lasley/Gamow, and none of these references provides motivation for such, nor would there be a reasonable or predictable expectation of success, as is required for an obviousness rejection. Duke/Reillo/Lasley/Gamow do not teach, suggest, or even contemplate a method for causing atoms, molecules, or compounds to bind to attachment sites which a virus

would normally attach to, thus preventing the virus from attaching, and ultimately preventing virus replication. They do not remotely contemplate regulating such a molecular pathway. Additionally, claim 9 recites the use of other gases, one of which must be nitrogen or nitrous oxide, which as discussed above in reference to claim 1 is not taught or suggested by Duke/Reillo/Lasley/Gamow. Because none of these elements of claim 9 are taught or suggested by Duke/Reillo/Lasley/Gamow, there would be no motivation to combine or modify the references, there would be no reasonable or predictable expectation of success, and in fact the combination of the references does not result in the invention of claim 9. Therefore, Applicant submits that claim 9 is not obvious over the combination of Duke/Reillo/Lasley/Gamow and requests that the rejection be withdrawn. Applicant asserts that the arguments as to claim 9 apply with equal force to its dependent claims.

Accordingly, if the scope and content of the cited prior art are properly considered as set forth above, it becomes clear that the combination of Duke/Reillo/Lasley/Gamow do not lead the ordinary skilled artisan to Applicants' presently-claimed invention as set forth in the claims.

For these reasons, Applicant submits that the obviousness rejection as to Duke/Reillo/Lasley/Gamow be withdrawn. Applicant further submits that the claims as amended are in condition for allowance.

Conclusion

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (434) 243-6103.

Respectfully submitted,

Date: October 21, 2008

*Rodney Sparks*  
Rodney L. Sparks  
Registration No. 53,625  
4931 Lake Tree Lane  
Crozet, VA 22932  
Telephone: (434) 243-6103  
Fax: (434) 924-2493